UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION) MDL No. 1456) Master File No. 01-12257-PBS) Subcategory Case No. 06-11337 	
THIS DOCUMENT RELATES TO:) Judge Patti B. Saris	
State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al. Case No: 1:03-cv-11226-PBS	Magistrate JudgeMarianne B. Bowler	

PLAINTIFFS' SUR-REPLY IN OPPOSITION TO DEFENDANT SANDOZ INC.'S MOTION FOR SUMMARY JUDGMENT

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Plaintiffs hereby submit the following Sur-Reply in support of their opposition to the motion for summary judgment filed by Defendant Sandoz Inc. ("Sandoz").

ARGUMENT

I. SANDOZ ACTED WITH THE REQUISITE SCIENTER

To establish liability under the California False Claims Act ("CA FCA"), California need not show that Sandoz acted intentionally, but merely that it acted with actual knowledge, deliberate ignorance, or reckless disregard of the relevant information when it reported false and inflated AWPs to the pricing compendia. *See* CAL. GOV'T CODE § 12650(b)(2).

As set forth in Plaintiffs' Motion for Partial Summary Judgment, Plaintiffs have established that Sandoz acted with the requisite scienter, so as to subject it to liability under the CA FCA. It is undisputed that throughout the relevant time period, Sandoz set AWPs for its products and reported those AWPs to the pricing compendia, including FDB. (CA Sandoz SOF ¶ 6.¹) Regardless of whether Sandoz was the first company to market and sell a particular generic product, or if it launched a particular product into a market already containing a competitive product, there was no relationship between the substantially and falsely inflated AWPs Sandoz reported to FDB and the prices at which its products were sold to the retail class of trade. (CA Sandoz SOF ¶ 19). As further set forth in Plaintiffs' Opposition to Sandoz's pending motion (docket no. 6786), Sandoz did not report its transactional prices, or any average or compilation of those prices, to the pricing compendia or to California as it products' AWPs. Nor has Sandoz ever disclosed or explained to Medi-Cal the fact that its AWPs were falsely inflated, or the differences between its falsely inflated AWPs and estimated or actual provider acquisition costs for its drugs.

¹ Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Sandoz Inc. (docket no. 6687) (hereinafter "CA Sandoz SOF").

Sandoz continues to claim it did not have the requisite scienter because California was "at all relevant times fully aware of the material facts relating to Sandoz' pricing practices." (Sandoz Reply Br. at 1.) Sandoz resorts to the same argument in claiming that the three year limitation period found in the CA FCA, and not the ten year limitation period, governs Plaintiffs' claims. However, as previously established in Plaintiffs' Opposition to Sandoz's Motion for Partial Summary Judgment, and in Plaintiffs' Motion for Partial Summary Judgment, that argument is meritless.

A. California's Possession of AMP/URA Data Does Not Relieve Sandoz of its Fraudulent Conduct.

Sandoz's principal argument is that because Sandoz provided California the AMPs for its drugs during the period 1991 through 1996,² and because California received URA data on Sandoz's drugs from CMS during the relevant time period, it could not have acted with the scienter required under the CA FCA when Sandoz reported its falsely inflated AWPs to Medi-Cal.

As established in Plaintiffs' Opposition to the pending motion, at no time did California use either the AMPs provided by Sandoz, or the URA information provided by CMS, to determine the actual acquisition cost paid by providers for the Sandoz drugs. Rather, as testified to by various employees of California's Department of Health Care Services, the AMPs confidentially received by California from Sandoz pursuant to the Supplemental Rebate Agreement were used only for the calculation of supplemental rebates, and the URA data received from CMS was used only for the calculation of rebates pursuant to the Rebate Agreement between Sandoz and the Secretary of Health and Human Services. (See Sandoz SOF

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² Sandoz provided AMPs to California during this period pursuant to a Supplemental Rebate Agreement between the parties.

¶ 8.³) California was not required to use that information for *any* other purpose and, as stated in Plaintiffs' Opposition, California believed it could not do so pursuant to the confidentiality afforded to AMPs under federal law.

Without a single citation to any testimony or evidence whatsoever, Sandoz baldly claims that California has "misread" testimony which purportedly shows that California calculated AMPs from URAs. (Sandoz Reply Br. at 5.) This assertion is not true. Sandoz plays loose and fast with the truth in an attempt to sidestep evidence fatal to its motion.⁴ Sandoz also characterizes California's position that the confidentiality of AMP data was protected by federal law as "irrelevant." (Sandoz Reply Br. at 5.) In Massachusetts v. Mylan Labs, 608 F. Supp. 2d 127, 152 (D. Mass. 2008), the Commonwealth took exactly the same position regarding the confidentiality of AMPs as taken by California herein. This Court did not find the Commonwealth's position on the use of AMPs to be "irrelevant." Sandoz also states that "California considered AMP to be a more accurate reflection of transaction prices for drugs than AWP and other pricing indicators" (Sandoz Reply Br. at. 3), citing to the deposition testimony of Mike Namba, Vic Walker and Roy Takeuchi. (Sandoz SOF ¶ 7.) Again, Sandoz plays loose and fast with the facts. An accurate reading of the referenced testimony shows that the statements made by Mr. Namba and Mr. Walker reflect their understanding at the time of their depositions (both took place in 2009), and the cited statement made by Mr. Takeuchi is not made in

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³ Local Rule 56.1 Statement of Undisputed Facts in Support of Sandoz Inc.'s Motion for Summary Judgment (docket no. 6698) (hereinafter, "Sandoz SOF").

⁴ In its Reply in Support of its Local Rule 56.1 Statement of Undisputed Facts, at ¶ 7, Sandoz refers to the deposition of Craig Miller, a DHCS employee, to support this position. Actually, DHCS did not perform AMP/AWP comparisons on any particular drug, and Mr. Miller testified only that there was a general knowledge that AMPs were lower than AWPs. (*See* Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Sandoz Inc.'s Motion for Summary Judgment (docket no. 6787) at ¶ 4 (California did not calculate AMPs from URAs); Declaration of Steven Ross (docket no. 6788), Ex. 2 at 234:6-22.)

reference to AWP. *See Mylan Labs.*, 608 F. Supp. 2d at 150 (noting the difference between a witness' knowledge at the time of the deposition versus the time the false claim occurred).

Sandoz urges this Court to accept the proposition that, as a matter of law, the mere possession of AMPs and URA data by California, regardless of the limited and specific use to which that data was put (i.e., to administer the rebate program, exclusively) or the federally mandated confidentiality restrictions to which AMPs were at all times subject, constituted the type of full and cooperative disclosure from Sandoz mandated by case law if Sandoz is to demonstrate the absence of scienter. This argument was expressly rejected by this Court in Mylan Labs., 608 F. Supp. 2d at 152, and again most recently by this Court in its Order of January 27, 2009, allowing and denying motions for partial summary judgment in the drug pricing case brought by multiple New York counties against thirteen drug manufacturer defendants, including Sandoz. In Re Pharm. Indus. Average Wholesale Price Litig. (New York), No. 01-12257, (D. Mass. Jan. 27, 2010) (docket no. 6863). In *New York*, defendants argued (in the context of the setting of FULs by CMS), that the federal government had actual knowledge that defendants' reported prices were merely list prices, and not real prices, as CMS itself regularly received and was in possession of defendants' AMPs pursuant to CMS's administration of Medicaid federal rebates. As a result, the New York defendants (including Sandoz) argued that CMS should have known that defendants' published WACs and AWPs (on which CMS relied to set accurate FULs) were false. In decisively rejecting this argument, this Court stated:

But AMPs are statutorily prohibited from being used for reimbursement and must be held confidentially, and thus CMS could not have used AMP data in this way, and there is no evidence that it did. See Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008); 42 U.S.C. §1396r-8(b)(3)(D). Moreover, the Medicaid statute required CMS to set is prices on the basis of the Defendants' published prices, not the

Defendants' AMPs, and thus there is no reason to believe that CMS looked to the Defendants' AMP data in analyzing its reimbursements.

Id. at 28.

As noted above and discussed at length in Plaintiffs' Opposition brief, California did not use Sandoz's AMPs or URA data to set or analyze reimbursements, and could not have done so due to the confidentiality afforded to AMPs under federal law.

In their Opposition to Sandoz's motion, Plaintiffs additionally established that the Generic Pharmaceutical Association ("GPhA"), the generic drug manufacturer trade association whose members include Sandoz, took the *explicit* position in correspondence sent to the United States Senate Committee on Finance, and to CMS, that AMPs were mistakenly perceived as market price indicators, and in fact they bore little relevance to market prices, and that AMPs were easily misinterpreted when payers, state agencies and consumers relied on them to indicate actual prices available in the marketplace. (Pls. Opp. at 8.) Plaintiffs further pointed out that a representative of Defendant Mylan met with Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at DHCS, and presented Dr. Gorospe with a "white paper" prepared for California by GPhA at the request of Mylan. The white paper explained to California GPhA's position that AMPs were not an adequate basis on which to calculate pharmacy reimbursement, and that using AMPs would not be an accurate way of calculating the price charged by a manufacturer to consumers. (Pls. Opp. at 8-9.) At all times herein, Sandoz agreed with the position on AMPs taken by GPhA.

In its Reply, Sandoz goes to remarkable lengths to discredit the position on AMPs (i.e., that AMPs were an unreliable basis on which to calculate pharmacy reimbursement) taken by its own trade association. As this Court will note, Sandoz concludes again that GPhA's position on AMPs is not relevant and, in any event, California's position is not supported by "any fair

reading" of the GPhA letters and white paper. Once again, Sandoz ignores the facts. A "fair reading" of the GPhA materials referenced by Plaintiffs in fact shows that the objection expressed by GPhA regarding the use of AMPs as the basis for pharmacy reimbursement (which objection Sandoz completely agreed with) was based on the definition of AMP and the methods upon which it was calculated by drug manufacturers, notwithstanding the changes proposed in the DRA. A "fair reading" of these materials shows that it was the position of GPhA (and of Sandoz) that AMPs were not reflective of actual market prices, again notwithstanding the changes proposed in the DRA. GPhA also expressed additional concerns aimed at specific changes proposed in the DRA (such as lack of confidentiality). As discussed by Plaintiffs in their Opposition to the pending motion, Sandoz cannot have it both ways, representing now to this Court that AMPs represent actual provider costs for its drugs, yet also taking the position that AMPs should not form the basis for pharmacy reimbursement because they bear no relevance to actual market prices.

B. Caselaw Does Not Support Sandoz's Position.

There is no reported caselaw which supports the position taken herein by Sandoz that the mere possession of AMP/URA data imparts knowledge to the government of actual acquisition prices or mega-spreads. The only caselaw on the subject, *Mylan Labs*. and *New York*, stand for the exact opposite position. Similarly, there is no caselaw supporting the position taken by Sandoz that the State's receipt of AMPs pursuant to a rebate contract, or the transmission of URAs to the State from CMS, amounts to the full disclosure required to obviate scienter under any False Claims Act.

Sandoz also insists on misapprehending the degree of full and complete disclosure required to prevail on its "government knowledge" defense. As this Court has explained,

[e]ven those cases that have found government knowledge to negate the element of falsity have required that the government *possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false*; some have further required that the government actually approve of those true facts.

Mylan Labs., 608 F. Supp. 2d at 149 (emphasis added). This Court further stated in New York that "[t]o prevail on a government knowledge defense, Defendants must produce admissible evidence that New York or its agencies knew the actual true facts, and that they ordered, asked for, approved, or decided as a policy matter to acquiesce in the Defendants' reporting of false prices." New York, No. 01-12257 at 25 (emphasis added). Sandoz would therefore have to show undisputed evidence that not only did it make full and timely disclosure of its fraudulently inflated AWPs, but that California formally and affirmatively approved of the alleged wrongful price reporting conduct. Sandoz has made no such showing.

According to the Second Circuit, "the statutory basis for an FCA claim is the defendant's knowledge of the falsity of its claim, which is not automatically exonerated by any overlapping knowledge [of] government officials." *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1156 (2d Cir.), *cert. denied*, 508 U.S. 973 (1993). Similarly, the Ninth Circuit has stated "[t]hat a defendant has disclosed all the underlying facts to the government may...show that the defendant had no intent to deceive." *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991). The Ninth Circuit later reinforced this requirement in *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321 (9th Cir. 1995) in which relator, a former employee of defendant defense contractor, brought a *qui tam* action alleging defendant submitted false claims based on allegedly false testing and performance of communication and navigation systems on an attack helicopter. In affirming the trial court's directed verdict for defendant, the court found that information

flowed freely between the Army and defendant, and that "[o]verwhelming evidence established a pattern of cooperation between the Army and defendant during the course of a complicated, sophisticated, and highly technical military procurement program." *Id.* at 326.

Oblivious to such precedent, Sandoz apparently asserts that any shred of information acquired by California which would have suggested even an inference of the general disparity between Sandoz's fraudulently inflated AWPs and any other measure of provider costs is sufficient to obviate scienter. Once again, the caselaw cited by Sandoz to support this implausible proposition in fact reinforces Plaintiffs' position. In United States v. Shasta Services, Inc., 440 F. Supp. 2d 1108 (E.D. Cal. 2006), an unsuccessful California Department of Transportation (CalTrans) bidder filed a qui tam suit against the winning bidder, alleging noncompliance with a bidding requirement. An investigation established that the defendant had complied with all bidding requirements and had, in particular, fully disclosed its compliance efforts immediately after submitting its winning bid, and had later provided additional full disclosure during the investigation. Id. at 1110-11. Granting the governments' motions to dismiss, the Court noted "[t]he facts show that there ha[d] been full disclosure as to the particulars concerning [defendant's] bid both before CalTrans awarded the project in question to [defendant], and before any claim for payment was submitted by [defendant]." Id. at 113 (emphasis added).⁵

As Plaintiffs noted in their Opposition to the pending motion, the only "disclosure" made by Sandoz to California were AMPs which Sandoz provided to California for the period 1991 through 1996 pursuant to a supplemental rebate agreement. At no point did Sandoz <u>ever</u> provide California with its actual transactional prices, or provide any explanation to California regarding

⁵ In its Reply, Sandoz also cites to *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854 (2001). Plaintiffs discussed this case at length in their Opposition to the pending motion, noting that the facts in that case also bolster Plaintiffs' position.

the difference between those prices and its falsely inflated AWPs. Sandoz has failed to establish the appropriate level of government knowledge sufficient to allow this Court to determine that, as a matter of law, Sandoz acted without the scienter required under the CA FCA.

II. CALIFORNIA'S CLAIMS ARE NOT BARRED BY THE STATUTE OF **LIMITATIONS**

Sandoz next argues that a "perfect storm" of pricing-related information, consisting of Sandoz's AMP/URA data, a 1996 OIG report, and the qui tam plaintiff's complaint, was at California's disposal well before 1999 and is thus sufficient, as a matter of law, to bar all claims that accrued prior to August 1999 under the statute of limitations. Sandoz fails utterly, however, to uphold its burden of proving that the California Attorney General's office had discovered or was on notice of the State's claim against Sandoz by July 1999. Sandoz is therefore not entitled to summary judgment on this "factually intensive" inquiry. See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 78 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009).

There is no dispute that a claim under the CA FCA is timely if filed within three years "after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed." CAL. GOV'T CODE § 12654(a); Debro v. Los Angeles Raiders, 92 Cal. App. 4th 940, 947 (2001). In California, the official charged with the responsibility to act is the Attorney General.⁶ The California Court of Appeal clarified this in State ex rel. Hindin v. Hewlett-Packard Co., 153 Cal. App. 4th 307 (2007), stating, "The

⁶ The statute was amended last year to codify the decision in State ex rel. Hindin v. Hewlett-Packard Co., 153 Cal. App. 4th 307 (2007) and now expressly states as follows: "A civil action under Section 12652 may not be filed more than three years after the date of discovery by the Attorney General or prosecuting authority with jurisdiction to act under this article or, in any event, not more than 10 years after the date on which the violation of Section 12651 was committed."

legislative history of section 12654 indicates that the phrase 'the official of the state or political subdivision charged with responsibility to act in the circumstances' was intended to apply to a public official such as the Attorney General, who has responsibility to act to protect the public fisc from false claims." *Id*; *see also id*. at 316 (observeing that, in proposing the amendment to Section 12654, the Legislature intended to "provide for a shorter statute of limitations of 3 years, instead of 10 years, when the violation is known *to the public agency defrauded by the false claim*. (Sen. Policy Com., Off. of Sen. Floor Analyses, Rep. on Assem. Bill No. 1441 (1987-1988) (Reg. Sess.) Sept. 4, 1987, italics added)." Accordingly, *Hindin* makes it clear that the limitations period does not begin to run until the Attorney General's office discovers the wrongdoing, since it is the agency with responsibility to act under the circumstances.

As used in Section 12654, the term "discovery" encompasses both actual and inquiry notice, in that the three-year statute of limitations is triggered when the responsible government official "either knows of the false claim or knows of facts which would lead a reasonably prudent person to suspect it." *Debro*, 92 Cal. App. 4th at 953. Sandoz insists such inquiry notice occurred here as a matter of law. Sandoz is sorely mistaken; it neither has nor can irrefutably establish that the specific facts in Plaintiffs' possession would have led a reasonably prudent person to suspect that, among the more than 550 generic drug manufacturers whose products were reimbursed by Medi-Cal, Defendant Sandoz was falsely reporting the AWPs for the particular drugs at issue in this action.

Sandoz's implicit reliance on the case of *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940 (2001) is misplaced. In *Debro*, the court addressed a *qui tam* action brought by an individual who was challenging a financing agreement involving the Oakland Raiders' use of a stadium owned by two local political subdivisions, the City of Oakland and the County of

Alameda. The false claim allegation was based on the loan agreement describing the transfer of funds to the Raiders as a loan rather than a gift; the issue on appeal was whether the action was time-barred under Section 12654 due to the discovery of the facts underlying the claims more than three years before the action was filed.

After holding that the term "discovery" includes constructive as well as actual knowledge, the court in *Debro* sought to determine the date when the government officials overseeing the agreement would have known of its supposedly improper terms. The court found that the facts known to the aggrieved parties prior to the signing of the loan agreement reasonably put such parties on inquiry notice of the Raiders' purported intention to *treat* the transaction as a gift, whether that was the legal effect of the loan agreement or not. These facts included, *inter alia*, the actual language of the loan agreement and a direct warning, before the loan agreement was signed, that the Raiders considered the payment a gift.

No such clear-cut facts are present here. As noted above, the AMPs and URA data did not disclose providers' actual acquisition costs, or the true facts regarding Sandoz's knowingly false inflation of its AWPs. The 1996 OIG report—which was based only on a limited survey and found merely that California pharmacists could purchase generic drugs, on average, for approximately 41.4% below their published AWPs—simply revealed that in some instances manufacturers' reported AWPs were higher than actual acquisition costs and that Medi-Cal thus was paying too much in general for drugs. The report lacked any suggestion of nefarious conduct by any individual drug manufacturer; any discussion that AWPs were being used as a marketing tool to promote drug sales; and any indication of the mega-spreads at the heart of this case.⁷ And while the 1998 *qui tam* complaint alerted the Attorney General to conduct of specific

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⁷ In any event, there is no evidence in this extensive record that responsible officials from the California Attorney General's office were on notice of the 1996 OIG report. *Hindin* makes clear that the statute of limitations is tolled

inhalant pharmaceutical manufacturers and of specific inhalant drug products, it neither identified Sandoz nor compelled the conclusion that this particular generic pill manufacturer had engaged in this fraudulent conduct. In fact, the only logical inference that the Attorney General's office could draw from its review of the original complaint and supporting data was that the companies named in the relator's complaint might have been guilty of causing the submission of false claims by inflating AWPs, but that the hundreds of other pharmaceutical companies whose products Medi-Cal covered were apparently not engaged in such fraud.⁸

Sandoz insists that the facts of which California was aware would have led a reasonably prudent person to suspect, and in turn make further inquiry into, the specific facts underlying the CA FCA violations alleged against this particular Defendant. This is an ineffectual argument in light of the vast number of drug manufacturers and the countless number of individual Medi-Cal claims such manufacturers caused to be submitted on an annual basis. See, e.g., United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 572 (10th Cir. 1995) (distinguishing, for purposes of the public disclosure bar, between the government's ability to identify individual wrongdoers from industry-wide allegations made against measurers of natural gas on federal and tribal lands, and the government's ability [or, more accurately, inability] to narrow its investigative focus based upon general—or even specific—allegations of Medicare fraud).

Continuing with its litany of unpersuasive arguments, Defendant Sandoz characterizes as "baseless" Plaintiffs' observation that in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) the Court's statute of limitations findings were not made at

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until such officials were on notice of a potential claim. Moreover, even if, arguendo, the OIG report was adequate to trigger the statutory period as to all generic manufacturers (which Plaintiffs dispute), the fact that Medi-Cal personnel were aware of the OIG report was not enough to trigger the statutory period.

⁸ This case cannot be analogized to cases where a Plaintiff has suffered a single injury and is held on notice to investigate claims against all actors. Here, California suffered multiple distinct and independent injuries from each Defendant's misconduct.

the summary judgment stage, but after a twenty-day, witness-laden bench trial. Such distinction is far from "baseless." Sandoz also ignores the myriad case law which confirms that the question of "[w]hether a plaintiff knew or should have known of an injury so as to trigger the running of a statute of limitations is, with rare exception, a jury issue." Cleveland v. Internet Specialties West, Inc., 171 Cal. App. 4th 24, 31 (2009). Sandoz's attempt to demonstrate that the instant case constitutes such a rare exception is woefully anemic. Although as noted by Sandoz, the courts did grant summary judgment on the basis of the statute of limitations in Levin v. Graham & James, 37 Cal. App. 4th 798, 805-06 (1995), Snoke v. Bolen, 235 Cal. App. 3d 1427, 1432-33 (1991), and *Gray v. Reeves*, 76 Cal. App. 3d 567, 577-78 (1977), in those cases the courts were presented with unambiguous evidence of the commencement of a fee dispute arising from professional services rendered (Levin) and injuries resulting from alleged acts of medical malpractice (Snoke, Gray). In sharp contrast to those cases, Sandoz fails to present undisputed facts which would establish, as a matter of law, that California either knew that Sandoz falsely reported its AWPs, or knew "facts which would lead a reasonably prudent person to suspect" such false reporting. See Debro, 92 Cal. App. 4th at 953. Summary judgment on this ground must also be denied.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Plaintiffs' Memorandum of Law in Support of their Motion for Partial Summary Judgment, and Plaintiffs' Opposition to Sandoz Inc.'s motion for summary judgment, Plaintiffs respectfully request that this Court deny Sandoz Inc.'s motion for summary judgment.

Dated: January 29, 2010 Respectfully submitted,

EDMUND G. BROWN JR.

Attorney General for the State of California

By: __/s/ Steven U. Ross

NICHOLAS N. PAUL

Supervising Deputy Attorney General

STEVEN U. ROSS

Deputy Attorney General

Bureau of Medi-Cal Fraud and Elder Abuse

Office of the Attorney General

1455 Frazee Road, Suite 315

San Diego, CA 92108

Telephone: (619) 688-6026

Fax: (619) 688-4200

Attorneys for Plaintiff, STATE OF CALIFORNIA

THE BREEN LAW FIRM, P.A.

By: /s/ James J. Breen

JAMES J. BREEN

The Breen Law Firm, P.A.

5755 North Point Parkway, Suite 260

Alpharetta, GA 30022

Telephone: (770) 740-0008

BERGER & MONTAGUE, P.C.

By: /s/ Susan S. Thomas

SUSAN S. THOMAS

Berger & Montague, P.C.

1622 Locust Street

Philadelphia, PA 19103

Telephone: (212) 875-3000

Attorneys for Relator,

VEN-A-CARE OF THE FLORIDA KEYS, INC.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 29, 2010, a copy to Lexis-Nexis for posting and notification to all parties.

____/s/ Steven U. Ross_____ STEVEN U. ROSS